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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

**Re: Prior Notice of Imported Food Under the Public Health
Security and Bioterrorism Preparedness and Response Act of
2002; Docket No. 02N-0278; 68 Fed. Reg. 5428 (Feb. 3, 2003)**

Dear Sir or Madam:

The Food Marketing Institute (FMI) welcomes the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) proposed rule to implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act or Act). ^{1/} Section 307 requires FDA to issue regulations requiring the submission of notice in advance of any importation of food into the United States. FMI supports necessary and appropriate measures to combat bioterrorism and appreciates the agency's efforts in attempting to implement the various provisions of the Act in the very short timeframe provided by Congress. FMI believes, however, that the agency's proposed implementation of the prior notice requirement is much more complex than intended by Congress and, indeed, significantly overreaches the authority granted to the agency under the Act. Moreover, it appears that the complicated and overreaching nature of the proposal would severely disrupt commerce, without increasing the security of food imports.

In recent years, there has been a marked increase in the global sourcing of food sold at retail. Unnecessary delays at border ports of entry would lead to inefficiencies in the supply chain, negatively affecting U.S. food retailers and consumers. This is especially apparent with respect to just-in-time deliveries of perishables -- a necessary

^{1/} FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of \$340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

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business practice of retailers since inventories of perishables are kept at a minimum to avoid unnecessary waste from spoilage.

FMI's primary concern with the proposal is with the unworkable nature of the proposed minimum prior notice deadline of noon the calendar day before arrival. The Institute believes that this "one-size-fits-all" approach would be unduly burdensome on industry and FDA. Accordingly, we recommend that FDA establish different minimum notification periods for different modes of transportation and/or different types of foods (i.e., perishables versus non-perishables). These and additional recommendations are outlined below.

I. Time of Prior Notice

It is our understanding that produce from Mexico and Canada is often ordered, packed, transported across the border, and delivered to a U.S. retailer within a matter of hours. Our members have advised that the same holds true for foods processed in foreign facilities close to a U.S. port of entry. Accordingly, FDA's minimum prior notice period of noon the calendar day before arrival -- at least twelve hours -- would disrupt the cross-border flow of fresh produce and processed foods. To ensure the continued smooth flow of food products into the United States without diminishing food security, the agency should allow for flexibility in the implementation of the prior notice requirement and can easily do so by establishing separate minimum notification time periods for different modes of transportation and/or different ports of entry, as authorized by Congress.

The Bioterrorism Act specifically authorizes the agency, in determining the length of the prior notice period, to consider, among other factors: the effect on commerce; the locations of the various ports of entry into the United States; the various modes of transportation; and the types of food imported into the United States. The proposal, however, would apply the same minimum prior notice deadline to all foods, regardless of whether they are highly perishable and/or from Canadian or Mexican foreign facilities located close to the U.S. border.

FMI encourages the agency to adopt a minimum prior notice period of not more than four hours for food arriving by train, truck, or other means at Canadian and Mexican border ports of entry to avoid unnecessary and costly delays as carriers lay idle while waiting for the minimum notice period to elapse. Idle carrier will in now way enhance food security and may, in fact, serve as an opportunity for malfeasance. For the same reasons, we also suggest adopting a four-hour minimum prior notice period for perishables such as produce or seafood. Because their value, quality, and shelf-life begin deteriorating immediately after harvesting, perishables are often sourced from foreign facilities or growers close to the U.S. border so that they can be delivered to U.S. retailers and other customers to replenish stock on a just in time basis. The proposed minimum prior notice period of noon the calendar day prior to arrival for all foods, regardless of perishability or the mode of transportation, would impose a minimum notification period of at least twelve hours and, thus, would not allow this practice to continue, creating an

effective trade barrier and unduly burdening retailers who rely on fresh produce from Canada and Mexico that they cannot otherwise obtain from U.S. suppliers.

With respect to non-perishables that do not diminish significantly in value every hour after they leave a processing facility, FMI believes that a longer minimum prior notice period – perhaps eight hours – might suffice. This same minimum period could be imposed on product transported by ocean carrier.

FMI believes that our suggested flexible approach to the minimum prior notice deadline would provide the agency with more than sufficient time to determine whether sampling/inspection is warranted. If agency staff cannot be present at relevant ports of entry to conduct inspections in a timely manner, the agency could place the product on hold, although this is certainly not the most desirable result. FMI believes that FDA must extend its hours of operation to 24-hour coverage at all ports of entry if it is to effectively implement the prior notice provision, as explained further below.

II. Amendments and Updates

If FDA were to decrease the minimum prior notice time period, it would certainly cut back on the number of amendments to product identity the agency would have to process under the proposal. FMI believes, however, that regardless of the length of the notification period, the agency's proposed prior notice scheme, including its provisions for amendments and updates, is so complex that it would severely impede the flow of commerce into the United States without improving food security.

A. Amendments Should Be More Flexible

For instance, FDA proposes to allow amendments to product identity two hours prior to the arrival of food at the U.S. port of entry. FDA states in the preamble that amendments could be used to change the type of food (e.g., romaine versus iceberg lettuce), but not the nature of the food (e.g., tomatoes versus lettuce.). The agency explains further that this would prohibit the current practice of "topping off" carriers with items of a different nature than those indicated in the initial prior notice submission.

Under the current distribution system, trucks traveling from Mexico to the United States, for example, travel from South to North picking up orders of different food items for various customers along the way. At times, the food products loaded onto the truck are different than what was ordered, due to unanticipated problems on the manufacturing lines, among other issues. In addition, if the shipper, not the retailer, is in control of the truck, it may decide to "top off" the truck to make up for wasted space without the knowledge of the importer. FDA's proposal to require cancellation and resubmission of prior notices for "topping off" with different foods would force trucks to sit idle for the duration of a renewed minimum prior notice period, which might be as long as 36 hours. Such impediments would lead to tremendous inefficiency as many trucks would simply not operate at full capacity rather than wait at the border for the notification period to elapse. With respect to those vehicles and trucks that must or choose to wait, the security of the food being transported would be placed at risk since it is not likely that the driver

of the vehicle would attend to it closely for the twelve to 36 hours until the notification period elapses, leaving the food held by the carrier susceptible to tampering by a third-party. Accordingly, FMI believes that the agency should allow the practice of "topping off" to continue, by allowing for amendments that would reflect changes in the nature of the food offered for import.

B. Updates to Port of Entry Should Not be Required

FDA also proposes to require updates to anticipated arrival information, including the port of entry, two hours prior to the article of food's arrival at the port of entry. The Bioterrorism Act, however, requires that only the anticipated port of entry -- not the actual port -- be listed in a prior notice submission. Moreover, the Act clearly states that the statute's prior notice provision "may not be construed as a limitation on the port of entry for an article of food." FDA's proposal to require importers to submit updates for changes to the port of entry two hours before arrival would necessarily limit the port of entry into which the food would be able to arrive if, within, for example, one hour prior to arrival, the truck decides to enter the United States through a port of entry different than the port indicated in the initial prior notice submission. Arrival at a port different than originally anticipated should not matter for purposes of the prior notice requirement if FDA were to staff all of its ports adequately, as requested below.

III. Additional Points of Concern

FMI is pleased to learn that the agency is designing the Prior Notice System to provide an automatic electronic acknowledgment of receipt of a complete prior notice submission, with a time and date "stamp," as requested in our initial "pre-proposal" comments to the agency. FDA, however, did not address numerous other suggestions raised in our initial comments. These and additional comments are addressed below.

A. FDA Availability

As noted above, FMI requests FDA to ensure that agency staff is available at every U.S. port of entry, twenty-four hours a day, seven days a week, for purposes of verifying prior notice submissions or conducting inspections and sampling. After all, food shipments arrive at U.S. ports of entry at all times, even on the weekends. Placing entire shipments that arrive after business hours on hold for several hours or days while waiting for inspectors to return to duty would severely disrupt the flow of commerce and lead to a major shortage of warehouse space.

B. Existing Prior Notice Systems

To avoid unnecessary duplication, FMI encourages the agency to make use of existing information collection systems (i.e., ABI/OASIS interface) in implementing the prior notice requirements. As acknowledged by FDA in the preamble, importers already submit much of the same information required by the Act and proposal into FDA's OASIS system through the Customs Automated Broker Interface ("ABI"), a part of Customs' larger Automated Commercial System ("ACS"). FDA would require much more information in a prior notice submission than is required by the Act. FMI recognizes that FDA and Customs determined that the ABI/OASIS interface could not be altered to accommodate the data requirements of the proposed prior notice regulation by the December 12, 2003 deadline. It does not appear, however, that the agencies considered whether the interface could be modified to accommodate the information required by the Act but not the excess information specified in the proposal.

FMI notes that FDA intends to allow prior notice to be submitted through Customs' Automated Commercial Environment ("ACE") once it is fully operational. Thus, the agency's proposed prior notice system is an interim provision that will be obsolete once ACE is fully operational, expected in 2005. It is, therefore, not readily apparent why the agency would use its limited resources to develop an entirely new system if limiting the information required in prior notice to that required by the Act would allow the submission of prior notice through existing information collection systems at a much lower cost.

C. Brand Names

FMI encourages the agency to delete the requirement to provide brand names in prior notice submissions. As proposed, importers would already submit the FDA product code, common or usual name of the food, manufacturer information and other details that would allow the agency to determine whether to inspect and/or sample the product. To also require brand names imposes an added burden on importers with no added value to the agency's determination of whether to inspect a specific product at the port of entry and, therefore, should not be required.

This is especially problematic for retailers with private label products that may have different brand names to reflect the retail stores in which they are sold, but are otherwise identical in terms of their packaging and composition. As we understand the current prior notice proposal, each of these products would require a separate notification, even though they are identical except for the retail store identified on the label. This is excessive and duplicative paper work that in no way enhances food security while adding significant cost to the distribution system.

D. Quantity

FDA should allow submission of approximate quantities, rather than the exact quantity described from smallest package size to largest container. Exact quantities are not always known by the minimum prior notice deadline; thus, importers would have to cancel or amend prior notice submissions on a regular basis to reflect actual quantities. Moreover, it does not appear that the proposed requirement to submit exact quantities would further the purpose of the prior notice requirement (i.e., to enable inspections at ports of entry) or improve food security.

E. Avoiding Duplication

FMI also advises FDA to consider several federal initiatives of the newly formed Department of Homeland Security ("DHS") and attempt to provide reciprocity for those federal programs that affect security of imported products, transport vessels, and source of origin. Specifically, the U.S. Customs Service ("Customs") has implemented several mandatory and voluntary programs, which should be considered, including:

- FAST: NCAP/FAST processing for FAST will begin in December of 2002. NCAP/FAST is the first completely paperless cargo release mechanism put into place by U.S. Customs. This paperless processing is achieved through electronic data transmissions and transponder technology. NCAP/FAST is highly automated and allows for the expedited release of highly compliant cargo from major importers, reducing congestion at our land borders. NCAP/FAST is the first step toward account based processing as each participant is pre-approved and assigned an ACE I.D. Further, NCAP programming development needs to take place under ACE so that account based (periodic billing) entry summary can be achieved.
- 24-Hour Advance Cargo Rule: The effective date of implementation for this rule was February 2, 2003. Carriers and/or automated NVOCC's are now required to submit a cargo declaration 24 hours before cargo is loaded aboard the vessel at a foreign port. This program allows the use of electronic information sharing and reporting.
- AMS (Participants and Port Listing): Customs is now posting participants and their associated ports from Customs' listing in the Automated Manifest System (AMS) for air, rail and sea. The inclusion of carriers on the list does not constitute any form of endorsement by U.S. Customs regarding the nature, extent, or quality of services provided by those carriers. The site will be periodically updated with new participants or changes in carrier services. Any questions that may concern specific capabilities of the carriers should be discussed with that specific service provider.

- C-TPAT: This voluntary program is a process through which the Customs Service meets with company representatives and potentially visits selected domestic and foreign sites to verify that the supply chain security measures contained in the C-TPAT participant's security profile are accurate and are being followed. C-TPAT is a joint government-business initiative to build cooperative relationships that strengthen overall supply chain and border security. C-TPAT recognizes that Customs can provide the highest level of security only through close cooperation with the ultimate owners of the supply chain, importers, carriers, brokers, warehouse operators and manufacturers.

F. Originating Country

The agency states in the preamble that its definition of originating country (i.e., the country from which the article of food originates) is "aligned with the principles proposed by the Agricultural Marketing Service guidance" in response to the 2002 Farm Bill. FMI strongly urges the agency to avoid linking the originating country definition for prior notice purposes with the complex and onerous AMS definition. Instead, the agency should use this opportunity to bring the definition in line with the U.S. Customs definition of country of origin under the Tariff Act.

G. Electronic Submissions

FMI requests the agency to allow paper, as well as electronic, prior notice submissions. It is inherently unfair to require companies or facilities that do not have access to the Internet to either hire an agent with access to make its prior notice submissions, expend large sums of money to purchase the computer and services that would be necessary to access the online system, or walk to the town library, as suggested in the preamble, to utilize the public computers that may have Internet access.

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We hope that you will consider the foregoing recommendations as you develop final regulations to implement Section 307 of the Bioterrorism Act. If we may provide any additional information in this regard, or if we may be of assistance in any other way, please do not hesitate to contact us.

Sincerely,



Deborah R. White
Associate General Counsel,
Regulatory Affairs